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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,337

12/29/2003

Mark H. Tuszynski

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07/18/2006

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EXAMINER

LIETO, LOUIS D

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/748,337

Applicant(s)

TUSZYNSKI, MARK H.

Examiner

Louis D. Lieto

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/20/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11, 12 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11, 12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/08/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed 1/09/2006 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-8, 11-12 and 14-18 are pending and under consideration in the instant application. The sections of title 35 U.S.C not included in this office action can be found in a previous office action. An action on the merits follows.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/09/06 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 11-12 and 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims have been amended so that they now contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure fails to

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recite the limitation of two or more delivery sites. Applicants have not indicated where in the specification support for this new limitation can be found. Further, a key word search of the specification fails to find disclosure of this limitation anywhere in the specification as initially filed. Therefore, since the specification as filed does not contain support for the term two or more delivery sites, it is considered to be new matter. See M.P.E.P. 608.04(a). Applicant is required to cancel the new matter.

Response to Arguments

Applicant's arguments filed 1/09/2006 have been fully considered but they are not persuasive. Applicant argues that their initial claim set is similar to a numerical range limitation as discussed in the cited case of *In re Wertheim*. However, in the instant case the range disclosed is an open-ended range of one, to a potentially infinite number of injection sites in the brain. This differs from the closed range discussed in *In re Wertheim*. Further, applicant has not specifically indicated where in their specification they contemplated delivering a neurotrophin to two or more delivery sites in the brain. As previously stated the specification does not clearly contemplate the specific limitation of "two or more delivery sites in the brain." Therefore it is still considered to be new matter.

Claims 1-8, 11-12 and 14-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for delivery of a vector comprising a nucleic acid encoding NGF or GDNF, operably linked to a promoter, at two or more sites, not more than about 10mm apart, to a mammalian brain to stimulate growth or sustain activity of neurons, does not reasonably provide enablement for a method for delivering any neurotrophin composition

comprising a transgene encoding any neurotrophin via various administration routes into one or more sites within the targeted region of a mammalian brain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are directed to a method for delivery of a therapeutic neurotrophin, such as NGF or GDNF, to targeted defective, diseased or damaged cholinergic neurons in a mammalian brain, at two or more sites, wherein each delivery site is no more than about 10mm from another delivery site, to ameliorate disease, such as Alzheimer's disease or Parkinson's disease *in vivo*.

It is noted that applicant's amendments to the claims of 7/19/05 removed any requirement in the body of the claim that the vector-encoded neurotrophin is expressed. Presently, claim 1 does not require that the vector-encoded neurotrophin is expressed, or that there is any positive step resulting from the practice of the claimed method. Neither the specification nor the art of record provide any guidance that administration of a vector-encoded neurotrophin, without expression of the neurotrophin has any use what so ever.

The specification fails to disclose that a vector encoding any neurotrophin can ameliorate any defect, disease or damage *in vivo*. The working examples only disclose that doses of AAV expressing β -NGF were well tolerated in rat brain *in vivo* and NGF expression was observed. The specification does not disclose any examples describing the direct administration of any vector-encoded neurotrophin, other than AAV expressing β -NGF, to any mammal other than a rat. Further, the specification does not describe that AAV expressing β -NGF, or any other viral vector encoded neurotrophin can ameliorate the defect, disease or damage in any mammalian brain. Further, Reichardt et al. teaches that while both NGF and NT-3 signal through TrkA

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receptors on the axons of developing neurons, only NGF supports survival and differentiation, NT-3 does not {Reichardt et al. (2004) Cell 118:141-3; Abstract; pg. 142, Figure 1}. Finally, the specification does not provide any guidance on the administration of GDNF *in vivo*, to treat diseases such as Parkinson's disease.

The relevant art of record teaches that delivery of a vector encoding human NGF to the brains of humans diagnosed with Alzheimer's disease appears to reduce the rate of cognitive decline and to induce neuronal growth {Tuszynski et al. (2004) Nature Med. 11:551-555; Abstract}. Further, the art teaches that delivery of a vector encoding human GDNF to the brains of a rat model of Parkinson's disease appears to increase locomotor activity and to promote the recovery of nigral dopaminergic tone {Lapchak et al. (1997) Brain Research 777:153-160; Abstract}. However the claims are drawn to broader range of subject matter than that enabled by the relevant art.

The claims are drawn to a method of gene therapy by using any vector expressing neurotrophin via various administration routes *in vivo*. However, the specification also does not provide an enabling disclosure for using any vector/promoter combination to express any neurotrophin *in vivo*, in order to produce any positive effect. Verma et al. states that in the past, the Achilles heel of gene therapy was gene delivery, and that, most of the approaches suffer from poor efficiency of delivery and transient expression of the gene {Verma et al. (1997) Nature, Vol. 389, page 239, column 3, paragraph 2}. These issues remain as current problems in the field of gene therapy. Pfeifer and Verma state that even "though gene therapy holds great promise for the achievement of this task, the transfer of genetic material into higher organisms still remains an enormous technical challenge {Pfeifer and Verma (2001) Annu. Rev. Genomics. Hum. Genet.

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2:177-211; pg. 177, pgph 1}. Johnson-Saliba et al. concurs stating that “although thousands of patients have been involved in clinical trials for gene therapy, using hundreds of different protocols, true success has been limited. A major limitation of gene therapy approaches, especially when non-viral vectors are used, is the poor efficiency of DNA delivery.” {Johnson-Saliba et al. (2001) Curr. Drug. Targets 2:371-99; Abstract}. Such problems with delivery continue to plague the field of gene therapy. Shoji et al. has characterized the current state of the art as the “tragic failure of gene therapy” because of poor delivery of gene based-medicines due to the lack of an appropriate vector that “fulfills the necessary requirements, including high transfection efficiency, non-toxicity, non-pathogenicity, non-immunogenicity, [and] non-tumorigenicity.” {Shoji et al. (2004) Current Pharmaceutical Design 10 :785-796}. Therefore, for the reasons stated above, a practitioner in the art would be unable to predict that any neurotrophin encoded by a vector would have therapeutic activity in a mammalian brain and would ameliorate any defect, disease or damage and thus could not predict how to practice the invention in a manner commensurate in scope with the claims without undue and extensive experimentation.

Given the lack of guidance in the specification and the teachings in the art, a skilled practitioner would be unable to predict how to practice the invention as claimed, except as a method for delivery of a vector comprising a nucleic acid encoding NGF or GDNF, operably linked to a promoter, at two or more sites, not more than about 10mm apart, to a mammalian brain to stimulate growth or sustain activity of neurons, without undue and extensive experimentation.

Response to Arguments

Applicant's arguments filed 1/09/2006 have been fully considered but they are not persuasive. Applicant argues that the '058, '306 and '431 patents should be given their "full faith and credit," and that that since the enablement issues were resolved in applicant's favor in these patents they should be dropped in the instant application. In most instances applicant is nominally correct, however applicant should note that each application is examined individually, based on its own merits. Where, as in the present case, there are art and/or enablement issues that impact previously issued claims the rejection can still be made after it is reviewed and signed by the director of the TC. For example see the office action of 1/19/05, which was signed by Jasmine Chambers, the director of TC 1600. Therefore the rejection was initially properly made and is presently properly maintained.

Next applicant argues that the examples in the specification and the declaration of Dr. Mark Tuszynski enable the instant invention for targeting different populations of neuron in different regions of the brain. It is noted that after careful review of the prior submitted art the scope of enablement has been changed from that previously applied by the examiner. Specifically, the rejections over methods of treatment for Alzheimer's disease and Parkinson's disease were dropped. However, the rejection over the general method is maintained as set forth above. Further, applicant still has not indicated where in the specification or the prior art there is sufficient guidance to practice the claimed invention in a manner commensurate in scope with their claims. It is noted that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. In re Goodman, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991). Case law teaches (Ex parte

Forman, 230 USPQ 546,547 (BPAI 1986)) that “the disclosure of a patent application must enable practice of the invention claimed without undue experimentation”, wherein factors involved in the determination of undue experimentation were deemed to include “the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims.” In the instant case, the teachings of the specification fail to enable the invention in view of the breadth of the claims and the unpredictability in the art. Therefore the rejection is maintained for reasons of record as stated above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 11-12 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a method for delivery for delivery of a therapeutic neurotrophin to targeted neurotrophin-receptor neurons in the mammalian brain in order to stimulate growth or sustaining activity. However, there is no language in the body of the claim (e.g. from comprising on) that relates back to the pre-amble. Further, the body of the claim does not require any positive outcome. Therefore the metes and bounds cannot be determined. Claims 2-8, 11-12 and 14-18 depend from claim 1.

Double Patenting

The rejection of claims 1-17 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-17 of prior U.S. Patent No. 6,683,058 is withdrawn in view of applicant's amendment to the claims. However, this withdrawal is based on applicant's addition of new matter to the claims in the amendment of 7/19/05. Upon withdrawal of the new matter the rejection will be reinstated. Further, an obviousness-type double patenting has not been made over the '058 patent since applicant filed a terminal disclaimer over the '058 patent on 7/19/05.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2,5,6,11,12 and 18 are rejected on the ground of nonstatutory double patenting over claims 1-6,8, and 10 of U. S. Patent No. 6,815,431 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The claims are drawn to delivery of a vector encoded neurotrophin, such as NGF or GDNF to a mammalian brain, at one or more sites, to treat diseases such as Parkinson's disease.

The rejection of claims 1, 11, 12 and 13-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2,3, 4 and 5, of U.S. Patent No. 6,451,306, is withdrawn in view of applicant's filing of a terminal disclaimer on 11/08/05.

Response to Arguments

Applicant's arguments filed 1/09/2006 have been fully considered but they are not understood. Applicant states that they are withdrawing the terminal disclaimer filed on 7/19/05, over U.S. Patent No. 6,683,050. It is suggested that applicant meant to withdraw the terminal disclaimer over U.S. Patent No. 6,683,058. However, it is not clear if that is in fact their intention. Applicant is advised that if they do withdraw the terminal disclaimer filed over U.S. Patent No. 6,683,058, an obviousness-type double patenting will be made over the pending claims of the instant application and the '058 patent. Finally, applicant is advised that their attempt to withdraw the terminal disclaimer is improper. In order to withdraw a previously filed terminal disclaimer applicant is required to submit a petition to the Office of Petitions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Martinez-Serrano et al. { Martinez-Serrano et al. (1995) J. Neuroscience 15:5668-5680}.

Martinez-Serrano et al. provides guidance on a method of administering a therapeutic neurotrophin composition, comprising a neural progenitor cell line transfected with a MMLV retrovirus encoding a mouse NGF cDNA into the brain of a rodent in more than one location (pgs. 5669-5671). Martinez-Serrano et al. teaches delivering the neural progenitor cell line to two locations no more than about 10mm apart (pg. 5670, Materials and Methods). Further, Martinez-Serrano et al. teaches that the engrafted cells blocked over 90% of the cholinergic cell loss in fimbria-fornix induced lesions (Abstract; pg 5677, Figure 6; pg. 5678, Figure 8). The engrafted cells migrated for a distance of 1-1.5 mm from the implantation sites (Abstract; pg 5674, col. 1, pgph 3) and expressed NGF (pg. 5674, col. 2, pgph 1). Finally, Martinez-Serrano et al. teaches that the cells expressed a transgene encoded NGF within 500 um of a target cell (pg 5675, Figure 4; pg 5676, Figure 5). Thus, by teaching all the limitations of the claims as written, Martinez-Serrano et al. anticipates the instant invention as claimed.

Response to Arguments

Applicant's arguments filed 1/09/2006 have been fully considered but they are not persuasive. Applicant argues that the guidance of Martinez-Serrano does not teach or suggest

that expressed growth factor could be therapeutically administered to reverse the effects of existing degeneration among brain cells, nor does the paper encourage administration of growth factor directly into brain cells. Applicant is advised that they are arguing limitations not present in the claim. Applicant should note that , the intended use of the method does not constitute a step in the method as claimed. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps are able to stand alone. In re Hirao , 535 F.2d 67, 190 USPQ 15 (CCPA 1976); Kropa v. Robie , 88 USPQ 478, 481 (CCPA 1951). In the instant case the claimed method comprises a method of delivering a neurotrophin transgene into two or more delivery sites in the brain, wherein each delivery site is no more than about 10 mm from another delivery site. Applicant argues that Martinez-Serrano et al. does not encourage the administration of growth factor directly into the brain as is encompassed by the present claims. Applicant's interpretation of their claimed invention is contrary to language of the claims. The claims are unambiguously drawn to delivery of a neurotrophin transgene, which is patentably distinct from a growth factor, since a transgene is a nucleic acid, while a growth factor is a protein. Applicant argues that Martinez-Serrano et al. does not teach that growth factor may be introduced into more than one delivery site less than 10mm apart. Again, applicant's claims are drawn to administration of a transgene encoding a neurotrophin, not a growth factor. Further applicant's claims do not limit how that transgene is administered and so would be anticipated by administration of a cell comprising a transgene, which may be encoded within a viral vector (see, Martinez-Serrano et al.; (pg. 5670, Materials and Methods; col.2). The rejection is maintained for reasons of record as stated above and in the office action of 9/08/05.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,3,8,11,12,14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lapchak et al. (1997) Brain Research 777:153-160, in view of Martinez-Serrano et al. {Martinez-Serrano et al. (1995) J. Neuroscience 15:5668-5680}

Lapchak et al. provides guidance on a method of treating Parkinson's disease by administering an adenoviral vector that encodes human GDNF into the substantia nigra of a rat model of Parkinson's disease (Abstract; pg. 154, Materials and Methods). Wherein treatment appears to increase locomotor activity and to promote the recovery of nigral dopaminergic tone (Abstract). Wherein 8ul of saline comprising the Ad-GDNF is delivered to the rat brain via direct injection pg. 155, Materials and Methods). Lapchak does not teach that the vector is delivered to two or more sites in the brain no more than about 10mm from each other.

Martinez-Serrano et al. supplements the guidance of Lapchak et al. by teaching on a method of administering a therapeutic neurotrophin composition, comprising a neural progenitor cell line transfected with a MMLV retrovirus encoding a mouse NGF cDNA into the brain of a rodent in more than one location (pgs. 5669-5671). Martinez-Serrano et al. teaches delivering the neural progenitor cell line to two locations no more than about 10mm apart (pg. 5670, Materials and Methods). Further, Martinez-Serrano et al. teaches that the engrafted cells blocked over

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90% of the cholinergic cell loss in fimbria-fornix induced lesions (Abstract; pg 5677, Figure 6; pg. 5678, Figure 8). The engrafted cells migrated for a distance of 1-1.5 mm from the implantation sites (Abstract; pg 5674, col. 1, pgph 3) and expressed NGF (pg. 5674, col. 2, pgph 1). Finally, Martinez-Serrano et al. teaches that the cells expressed a transgene encoded NGF within 500 um of a target cell (pg 5675, Figure 4; pg 5676, Figure 5).

Based on the guidance provided by Lapchak et al. on a method of treating Parkinson's disease by delivery of an adenoviral vector that encodes human GDNF into one site in the brain, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the teachings of Lapchak et al. with those of Martinez-Serrano et al. by delivering the vector to two or more sites in the brain no more than about 10mm from each other.

A practitioner in the art would be motivated to modify the teachings of Lapchak et al. with the teachings of Martinez-Serrano et al. in order to maximize GDNF expression in the substantia nigra, thus inducing the maximize the increase in locomotor activity and the recovery of nigral dopaminergic tone.

The person of ordinary skill in the art would have had a reasonable expectation of success because delivering the Ad-GDNF vector of Lapchak et al. to two sites within the brain would have been routine practice in the art at the time of filing.

No claims allowed.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto
Patent Examiner
Art Unit 1632



DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/630